9. 510 (k) Summary of Information Respecting Safety and Effectiveness

A. Legally Marketed Device.

Qualis claims substantial equivalence to K-Y Warming Ultra Gel Personal Lubricant (K040340), currently in commercial distribution by Personal Products Company Division of McNeil-PPC inc..

B. Device Description.

Personal Warming Gel is a non-sterile, clear, non-staining, non-greasy, liquid gel used as a personal lubricant. This product is highly lubricous and may be used with or without a latex condom during intimate sexual activity.

C. Intended Use.

Personal Warming Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.

D. Comparison with Predicate Device.

A summary comparison of the features of Personal Warming Gel and the Predicate Device K-Y Brand Warming Ultra Gel Personal Lubricant is provided in Table 1.

E. Performance Data

Non-Clinical Studies.

1. Stability.

Personal Warming Gel has successfully passed 90 day accelerated stability.

2. Preservative Effectiveness.

An anti-microbial preservative challenge has been completed for Personal Warming Gel. The Preservative Effectiveness Study Report is in Attachment E.

3. Comparison with Predicate Device.

Personal Warming Gel was compared to K-Y Brand Warming Ultra Gel Personal Lubricant on the basis of perceptual qualities, physical and chemical properties, ingredients list review, label claims, and packaging. The result of this review was an acceptable comparison. See Attachment B for the Shuster comparison Report.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Mr. Mike Peterson
Quality Assurance Manager
Qualis Inc.
4600 Park Ave
DESMOINES IA 50321

Re: K050211
Trade/Device Name: Personal Warming Gel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 NUC
Dated: January 18, 2005
Received: January 31, 2005

Dear Mr. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050211

Device Name: Personal Warming Gel

Indications For Use: Personal Warming Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050211